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EXAMINING GROUP 1600

PATENT  
Attorney Docket No. 201895

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

Falck-Pedersen

Application No. 08/653,114

Filed: May 24, 1996

For: ADENOVIRUS GENE  
EXPRESSION SYSTEM

Art Unit: 1632

Examiner: R. Schnizer

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**PENDING CLAIMS AFTER AMENDMENTS MADE  
IN RESPONSE TO OFFICE ACTION DATED MARCH 15, 2002**

1. An adenoviral vector for expressing a heterologous gene(s) in a host cell, comprising at least one insertion site for cloning a selected heterologous gene, and, in an orientation opposite to the direction of transcription of the adenoviral region into which it is inserted, (a) a heterologous promoter positioned upstream from said at least one insertion site, wherein, upon cloning of the selected heterologous gene into said at least one insertion site, said gene is under the regulatory control of said heterologous promoter; (b) a eukaryotic splice acceptor and splice donor site positioned downstream of said promoter and upstream of said at least one insertion site; and (c) a polyadenylation sequence positioned downstream of said insertion site.

3. The adenoviral vector according to Claim 1, wherein said heterologous promoter is a mouse cytomegalovirus early promoter, or an effective expression promoting fragment thereof.

4. The adenoviral vector according to Claim 1, wherein said polyadenylation sequence is the mouse  $\beta$ -globin polyadenylation sequence.

9. The adenoviral vector according to Claim 1, wherein said at least one insertion site further comprises a second insertion site for insertion of a second heterologous gene.

17. The adenoviral vector according to Claim 1, wherein said adenoviral vector further comprises heterologous DNA inserted in said at least one insertion site.

18. A host cell infected with the adenoviral vector of Claim 17.

19. A method for producing a selected protein, comprising culturing a host cell which has been infected with the adenoviral vector of Claim 17, wherein said heterologous DNA encodes a selected protein, whereupon said selected protein is produced.

20. A method of delivering a heterologous gene to an animal heart *in vivo*, wherein the method comprises administering to the animal heart an adenoviral vector comprising, in an orientation opposite to the direction of transcription of the adenoviral region into which it is inserted, (a) a heterologous gene; (b) a promoter positioned upstream from the heterologous gene, the heterologous gene being under the regulatory control of the promoter; (c) a eukaryotic splice acceptor and donor site positioned downstream of the promoter and upstream of the heterologous gene; and (d) a polyadenylation sequence.

21. The adenoviral vector of claim 1, which comprises at least one insertion site for cloning a selected heterologous gene, and, in an orientation opposite to the direction of adenoviral E1 gene transcription, (a) a heterologous promoter positioned upstream from said at least one insertion site, wherein, upon cloning of the selected heterologous gene into said at least one insertion site, said gene is under the regulatory control of said heterologous promoter; (b) a eukaryotic splice acceptor and splice donor site positioned downstream of said promoter and upstream of said at least one insertion site; and (c) a polyadenylation sequence positioned downstream of said insertion site.

22. The adenoviral vector of claim 1, which comprises at least one insertion site for cloning a selected heterologous gene, and, in an orientation 3' to 5' relative to adenoviral E1 gene transcription, (a) a heterologous promoter positioned upstream from said at least one insertion site, wherein, upon cloning of the selected heterologous gene into said at least one insertion site, said gene is under the regulatory control of said heterologous promoter; (b) a eukaryotic splice acceptor and splice donor site positioned downstream of said promoter and upstream of said at least one insertion site; and (c) a polyadenylation sequence positioned downstream of said insertion site.